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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,037	10/27/2000	Peter Bennett Duff Whyte	U013032-6	8344
7590	10/20/2004			
William R. Evans c/o Ladas & Parry 26 West 61st Street New York, NY 25858				
			EXAMINER WARE, DEBORAH K	
			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/702,037

Applicant(s)

WHYTE, PETER BENNETT DUFF

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 28-73 are presented for reconsideration on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment filed July 12, 2004, has been received and entered.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on March 17, 2004 was received. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### ***Claim Rejections - 35 USC § 103***

Claims 28-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over AU-A-63136/94 and WO 97/16977, both in view of Clark et al, all cited of record.

Applicant's arguments filed July 12, 2004, have been fully considered but they are not persuasive. The argument that the prior art teaches removal of casein is noted, however, in particular WO 97/16977 actually teaches the presence of casein and that is optional that it be removed in terms of a preferred embodiment. It would have been obvious to leave the casein in the colostrum fraction because it is a protein and one of skill in the art would have expected successful results with its presence in the fraction while using it to change body composition and/or physical work capacity of a subject. Protein is a well known component for enhancing physical work performance. The art clearly teaches spray drying as a useful technique for drying the colostrum fraction product. The argument that the colostrum product would not have been expected to

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provide successful results because the casein and growth factors would have been degraded in the gut is noted.

However, the colostrum is dried and hence it is preserved and so these components would not be degraded in the gut and a subject will still be able to benefit from them in terms of improving their body composition and physical work capacity. Further, to vary the ratio of components is well within the skill of an ordinary artisan. The applied references each teach colostrum and as applied in combination the process steps are taught to include the presence of growth factors and casein in the colostrum and further teach the step of drying. Also to apply the same colostrum fraction to treat disorders of the gut of a subject is obvious for reasons discussed above and for those of record.

It is taught that colostrum is a food and promotes healing of the body composition by ridding the toxins and hence in doing so disorders of the gut would have been expected to be improved. Further, AU reference clearly teaches improving gut growth and development. Reduced fatigue would have also been expected because the art teaching (Clark et al) that fatigue is reduced is in direct correlation with the reduction of muscle damage during exercise. Hence with reduce fatigue the psychological perception of fatigue would have been also expected to be improved. The prior art does indeed teach freeze drying and the presence of casein and hence the claims are prima facie obvious.

No claims are allowed.

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The reference(s) cited on enclosed PTO-1449 Form are cited to further show the state of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

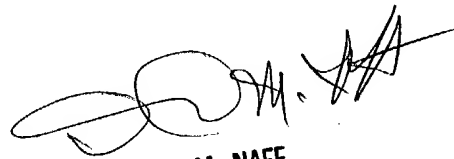
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah K. Ware  
October 2, 2004



DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1651